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| 10/534,377 | 05/09/2005 | Simon Cawthorne | 06275-454US1 100896-1P US | 2830 |

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| EXAMINER | |
|---|---|
| HAGHIGHATIAN, MINA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

| MAIL DATE | DELIVERY MODE |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/534,377 | CAWTHORNE, SIMON | |
| | Examiner | Art Unit | |
| | Mina Haghighatian | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/9/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

**Claims 1-16 are pending.**

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Trofast et al (WO 0053188).**

Trofast et al teach combinations of formoterol and budesonide for treating respiratory disorders such as asthma and COPD (see abstract and page 4). The formulations may be in a suspension form and are delivered by a nebulizer or metered dose inhaler. The combined active agents are mixed with excipients such s diluents and carriers and HFA propellants (see page 6). The dry powder formulations containing an additive, diluent or carrier could be either in agglomerated form or as ordered mixtures (see page 7).

Claims 9-12 are product-by-process claims and since it appears that the process does not functionally alter or affect the product (formulation), the process limitations are not given patentable weight. Claims 13-14 are drawn to a method of treatment, and depend on claim 9. Trofast et al teach treating asthma and COPD by administering a

formulation combination of formoterol and budesonide. All patentable limitations are met by the reference.

**Claims 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Gavin (WO 0178737).**

Gavin teaches combinations of formoterol and budesonide for treating respiratory disorders such as asthma and COPD (see abstract and page 4). The formulations may be in a suspension form and are delivered by a nebulizer or metered dose inhaler. The combined active agents are mixed with excipients such s diluents and carriers and HFA propellants (see page 6). The micronised active ingredients are weighed into an aluminum can, 1,1,1,2-tetrafluoroethane is then added from a vacuum flask and a metering valve is crimped into place (see page 8).

Claims 9-12 are product-by-process claims and since it appears that the process does not functionally alter or affect the product (formulation), the process limitations are not given patentable weight. Claims 13-14 are drawn to a method of treatment, and depend on claim 9. Gavin teaches treating asthma and COPD by administering a formulation combination of formoterol and budesonide. All patentable limitations are met by the reference.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1-8 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trofast et al (WO 0053188) in view of Keller et al (6,645,466).**

Trofast et al, discussed above, teach that the formulations may be in an ordered mixture, but lacks specific disclosure on stepwise addition of components.

Keller et al teach dry powder inhalation formulations and a method of improving moisture resistance of the dry powder formulations. In order to guarantee consistent production of the formulation, mechanical filling of the powder inhaler and correct dosage and release by the powder inhaler, the powder must be free-flowing (col. 1, lines 31-35). In order to meet the said requirements, the inhalable, i.e. present in microfine particles, constituents are mixed with pharmacologically inactive substances in order to obtain flowable powders (col. 1, lines 60-65). In principal, the constituents

can be mixed with one another in any desired sequence, where, however, mixing should expediently be carried out in such a way that the particles of the constituents- apart from the adhesion to the carrier particles- are essentially retained as such, i.e. are not destroyed, for example, by granulation and the like. According to a preferred variant, however, a preliminary mixture of magnesium stearate with the carrier can first be prepared and then the active compound particles can be mixed. Mixing can be carried out in a manner known per se, for example in a tumble mixer (col. 8, lines 46-67).

Although the combined references do not specifically disclose a process to minimize loss of one or more of the components of a formulation through adhesion to equipment surfaces, it has been shown that mixing the components in a stepwise fashion is known and practiced in the industry and would have produced the same formulations. In other words, the claims would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art.

**Claims 1-8 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trofast et al (WO 0053188) in view of Remington: The science and practice of pharmacy.**

Trofast et al, discussed above, teach that the formulations may be in an ordered mixture, but lacks specific disclosure on stepwise addition of components.

Remington teach production methods of producing and packaging pharmaceutical powders. It is disclosed that in manufacturing and extemporaneous preparation of powders, heavy trituration is an important step (see page 696). In describing trituration it is disclosed that triturations are dilutions of potent powdered drugs, prepared by intimately mixing them with a suitable diluent in a definite proportion by weight. The steps of triruration includes reducing the drug to moderately fine powder in a mortar, adding about an equal amount of diluent and mix well by thorough trituration in the mortar, successively add portions of diluent, trirurating after each addition until the entire quantity of diluent has been incorporated (see page 698).

Although the combined references do not specifically disclose a process to minimize loss of one or more of the components of a formulation through adhesion to equipment surfaces, it has been shown that mixing the components in a stepwise fashion is known and practiced in the industry and would have produced the same formulations. In other words, the claims would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
Patent Examiner
September 27, 2007